IFW

DOCKET NO.: ALZA-0143 **PATENT**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:

George V. Guittard, *et al.* **Confirmation No.: 8447**

Application No.: 10/645,715 **Group Art Unit: 1614**

Filing Date: August 20, 2003 **Examiner: George, Konata M.**

For: METHOD FOR MANAGEMENT OF INCONTINENCE

DATE OF DEPOSIT: **January 19, 2006**

I HEREBY CERTIFY THAT THIS PAPER IS BEING DEPOSITED WITH THE UNITED STATES POSTAL SERVICE AS FIRST CLASS MAIL, POSTAGE PREPAID, ON THE DATE INDICATED ABOVE AND IS ADDRESSED TO THE UNITED STATES PATENT AND TRADEMARK OFFICE, P.O. BOX 1450, ALEXANDRIA, VA 22313-1450

Wendy A. Choi

TYPED NAME: **Wendy A. Choi**
REGISTRATION NO.: **36,697**

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Pursuant to 37 CFR § 1.56 and in accordance with 37 CFR §§ 1.97-1.98, information relating to the above-identified application is hereby disclosed. Inclusion of information in this statement is not to be construed as an admission that this information is material as that term is defined in 37 CFR § 1.56(b).

☐ In accordance with § 1.97(b), since this Information Disclosure Statement is being filed either within three months of the filing date of the above-identified application, within three months of the date of entry into the national stage of

the above identified application as set forth in § 1.491, before the mailing date of a first Office Action on the merits of the above-identified application, or before the mailing date of a first Office Action after the filing of request for continued examination under § 1.114, no additional fee is required.

☒ In accordance with § 1.97(c), this Information Disclosure Statement is being filed after the period set forth in § 1.97(b) above but before the mailing date of either a Final Action under § 1.116 or a Notice of Allowance under § 1.311, or before an action that otherwise closes prosecution in the application, therefore:

☐ Certification in Accordance with § 1.97(e) is attached; or

☒ The fee of **$180.00** as set forth in § 1.17(p) is attached.

☐ In accordance with § 1.97(d), this Information Disclosure Statement is being filed after the mailing date of either a Final Action under § 1.113 or a Notice of Allowance under § 1.311 but before, or simultaneously with, the payment of the Issue Fee, therefore included are: Certification in Accordance with § 1.97(e); and the submission fee of **$180.00** as set forth in § 1.17(p).

☒ Copies of reference numbers **1 through 364** listed on the attached Form PTO-1449 are enclosed herewith.

☐ Copies of reference numbers on the attached Form PTO 1449 are not required to be submitted pursuant to the waiver of 37 CFR § 1.98(a)(2)(ii).

☐ Copies of references - are not being submitted because they were previously cited by or submitted to the U.S. Patent and Trademark Office in patent application number , filed for which a claim for priority under 35 U.S.C. § 120 has been made in the instant application.

☐ The relevance of those listed references which are not in the English language is as follows:

There are no listed references which are not in the English language.

REMARKS

Pursuant to 37 C.F.R. § 1.98, the art identified in the appended documents and other information and matters discussed below may be helpful to the U.S. Patent and Trademark Office (PTO) in its consideration of the above-identified patent application.

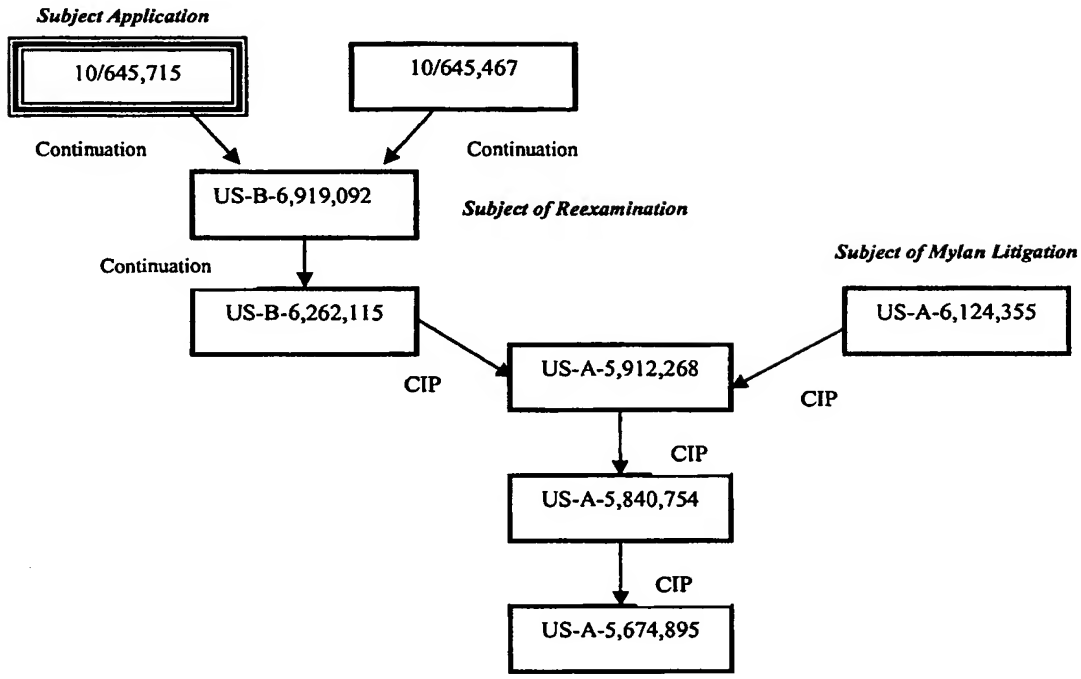
ALZA Corporation, the assignee of this application, has filed a Request for Reexamination of claims 1 to 23 of related U.S. Patent No. 6,919,092 ("092 Patent"). This application is a continuation of Application No. 09/785,805, which issued as the 092 Patent. The reexamination of the 092 Patent was assigned to Examiner Evelyn Mei Huang, and has been granted.

IMPAX Laboratories, Inc. and Mylan Pharmaceuticals Inc. have both filed certificates with the U.S. Food and Drug Administration, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certifications"), alleging that, *inter alia*, the claims of the 092 Patent are invalid either under 35 U.S.C. § 102(b) as anticipated and/or under 35 U.S.C. § 103(a) as obvious. ALZA does not agree, and believes that the references cited in the Paragraph IV Certifications, alone or in combination, do not render claims 1 to 23 of the patent unpatentable or invalid.

In addition, IMPAX alleges in its Paragraph IV Certification that ALZA engaged in inequitable conduct for failing to identify and disclose to the Office litigations involving U.S. Patent No. 6,124,355 and certain references that are identified in the accompanying Form PTO-1449. ALZA denies that it withheld any material information with the intent to mislead the Patent Office.

U.S. Patents Nos. 5,674,895, 5,840,754, 5,912,268, 6,124,355 (the "355 Patent"), and 6,262,115, which share a claim of priority with the instant patent application, are or have been the subject of litigation, *i.e., ALZA Corporation v. IMPAX Laboratories, Inc.,* Civil Action Nos. 03-04032-VRW (N.D. Calif.), *IMPAX Laboratories v. ALZA Corporation, Inc.,* Civil Action Nos. 03-04796-VRW (N.D. Calif.) (both N.D. Calif. Cases collectively referred to as the "IMPAX Litigations"), and *ALZA Corporation v. Mylan Laboratories, Inc.*, Civil Action No. 1:03CV61 (N.D. W.Va.) ("Mylan Litigation").

The 355 Patent is a continuation-in-part of Application No. 08/806,773, filed February 26, 1997, now U.S. Patent No. 5,912,268, which is continuation-in-part of Application No. 08/706,576, filed September 5, 1996, now U.S. Patent No. 5,840,754, which is a continuation-in-part of Application 08/445,849, filed May 22, 1995, now U.S. Patent No. 5,674,895.



The only litigation to proceed to trial is the Mylan Litigation concerning the 355 Patent. Both the Mylan and IMPAX courts interpreted the 355 Patent in the same way. As discussed more fully below, a final decision has been entered in the Mylan Litigation holding the 355 Patent claims in suit invalid and not infringed, and as a result Judgment was entered in the IMPAX Litigation concerning the 355 Patent without considering the merits. The litigations concerning patents other than the 355 Patent were dismissed after ALZA granted Mylan and IMPAX covenants not to sue.

ALZA is submitting in Appendix I a Form PTO-1449 listing, *inter alia.*, certain patents, printed publications, and other materials that came to the Patent Owner's attention during the above-noted litigations. A copy of each of the documents is included with the Form PTO-1449. The Examiner is requested to indicate consideration of each reference or document with an initial in the left hand column next to each reference or document.

As is typical in a patent litigation, Mylan and IMPAX raised a wide range of different defenses relating to the scope, validity, and enforceability of the 355 Patent, all of which are vigorously disputed by ALZA, but may be relevant in some cases to the pending claims. The Court entered judgment in Mylan's and favor invalidating the 355 Patent claims in suit. During the protracted proceedings, the litigants conducted extensive discovery and there were numerous motions and memoranda filed by the litigants with respect to various issues.

To the extent not precluded by the Protective Orders entered by the respective courts in the Mylan Litigation and IMPAX Litigations, Applicants' undersigned counsel is available to immediately provide a copy of all materials generated during these litigations (note that not all constitute prior art). ALZA has made an extensive and good faith effort to present disclosure of such materials that may be relevant to the prosecution of this pending application, namely materials that may be relevant to: (1) the identification and scope of patent and printed prior art; (2) the interpretation and scope of the claims in the pending application; and (3) application of the art to the claims in the pending application.

ALZA recognizes the burden placed on the Examiner by the large volume of materials being provided pursuant to the Information Disclosure Statement. To further facilitate the Examiner's consideration of these materials, but without attempting to usurp the Examiner's opportunity to fully consider each item, ALZA has in the table in Appendix II categorized the disclosure of each document generated in the Mylan Litigation and IMPAX Litigation, which may serve as a helpful guide to direct the Examiner to certain materials that may be relevant to specific subject matter and issues. Each document is categorized

according to whether it contains a discussion or disclosure of, or reference to, one or more of the following subjects; the drug oxybutynin; controlled release delivery of drug (oxybutynin or otherwise); and Ditropan XL – naturally there is a great deal of overlap and so, to some extent, these characterizations may be partially subjective. The chart also indicates whether the document is litigation related. Finally, in the last column, where a document has been referred to in briefs and other filings submitted by the parties in the litigations, a citation is given by reference to a Tab Number. For the Examiner's convenience, the briefs and other filings referred to by Tab Number in the chart have been collected and submitted in the bound volumes accompanying this Supplemental Information Disclosure Statement.

ALZA also submits herewith the Post-Trial Memorandum Opinion and Order that the District Court recently issued in the Mylan Litigation; this document is also listed on the enclosed Form PTO-1449. Although the District Court held the claims of the 355 Patent to be invalid in view of certain references, ALZA does not believe that this holding is relevant to examination of the pending claims. Indeed, the respective claims of the 355 Patent and the above-identified patent application differ from one another, as is apparent from even a cursory review. For example, representative pending claim 40 of the above-identified patent application is directed to a method for managing incontinence by orally admitting to a patient a dosage form of 5-250 mg of oxybutynin or its salt to provide a a substantially zero order rate of release over 24 hours. The limitation of a "substantially zero order rate of release" is not recited in any claim of the 355 Patent.[1] The other pending claims either depend directly or indirectly from claim 40 and thus recite the same limitation that is not recited the 355

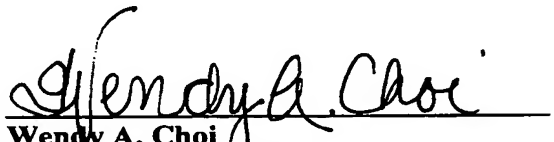
[1] ALZA believes that claims with these limitations are patentable and the District Court in the Mylan Litigation did not disagree. Rather, the court found (erroneously in ALZA's view) that the "zero-order release" and "constant rate of release" limitations are not included in the claims of the 355 patent. (Post-Trial Memorandum Opinion and Order, Reference 264 on Form PTO-1449, at page 40, footnote 12).

Patent claims. Thus, although ALZA wishes to make the Post-Trial Memorandum Opinion and Order of record for purposes of full disclosure, it is not believed to be relevant to patentability of the claims of the above-identified patent application.

ALZA respectfully requests that the Examiner indicate consideration of each reference or document with an initial in the left hand column next to each reference or document.

Please charge any deficiency or credit any overpayment to Deposit Account No. 23-3050. This form is submitted in duplicate.

Date: **January 19, 2006**



Wendy A. Choi
Registration No. 36,697

WOODCOCK WASHBURN LLP
One Liberty Place - 46th Floor
Philadelphia, PA 19103
Telephone: (215) 568-3100
Facsimile: (215) 568-3439

Form PTO-1449 Modified List of Patent and Publications Cited by Applicant (Use several sheets if necessary) U.S. Department of Commerce Patent and Trademark Office	Docket No. **ALZA-0143**	Application No. **10/645,715**
	Applicant **George V. Guittard, et al.**	
	Filing Date **August 20, 2003**	Group **1614**
	Confirmation No. **8447**	

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
	1	Data Processed Using Dissprof Program (V1.1), Oxybutynin C1, **Joint Exhibit 25, November 24, 2003** MYLAN 1014396-1014492
	2	Skelly, J.P. et al., "*In Vitro* and *In Vivo* Testing and Correlation for Oral Controlled/Modified-Release Dosage Forms", *Pharmaceutical Research,* **1990,** 7(9), 975-977, **Joint Exhibit 67**
	3	Theeuwes, F. et al., "Osmotic Delivery Systems for the β-Adrenoceptor Antagonists Metoprolol and Oxprenolol: Design and Evaluation of Systems for Once-Daily Administration, *Br. J. Clin. Pharmac.,* **1985,** 19, 695-765, **Joint Exhibit 81,**
	4	Oxybutynin, ALZA/TDC Meeting, **Friday July 15, 1993,** Palo Alto, Ca. **Defendant's Exhibits DX 00028,** DXL-016926 thru DXL-016976
	5	Ballard, B.E., "Prolonged-Action Pharmaceuticals", Chapter 91, **Defendant's Exhibit DX 00403,** 1594-1613
	6	Corrigan, O.I. et al., "Influence of Dissolution Medium Buffer Composition on Ketoprofen Release from ER Products and in Vitro—in Vivo Correlation", *International Journal of Pharmaceutics,* **2003,** 147-154, **Defendant's Exhibit DX 00408**
	7	Frick, A. et al., "Biopharmaceutical Characterization of Oral Controlled/Modified-Release Drug Products. In Vitro/in Vivo Correlation of Roxatidine", *European Journal of Pharmaceutics and Biopharmaceutics,* **1998,** 46, 313-319, **Defendant's Exhibits DX 00411**
	8	Drug Class Review on Urinary Incontinence Drugs", Final Report, **February 2003,** Oregon Health & Science University, **Defendant's Exhibit DX 00431**
	9	Oregon Health Resources Commission, Urinary Incontinence (Update Report) **Update #1, March 2004,** 12 pages, **Defendant's Exhibit DX 00432**
	9B	Ouslander, J.G. et al., "Pharmacokinetics and Clinica Effects of Oxybutynin in Geriatric Patients", *The Journal of Urology,* **1988,** 140, 47-50, **Defendant's Exhibit DX 00433**
	10	Qiu, Y. et al., "Once-a-Day Controlled-Release Dosage Form of Divalproex Sodium II: Development of a Predictive *In Vitro* Drug Release Method", *Journal of Pharmaceutical Sciences,* **November 2003,** 92(11), 2317-2325, **Defendant's Exhibit DX 00437**

EXAMINER	**DATE CONSIDERED**

Form PTO-1449 Modified List of Patent and Publications Cited by Applicant (Use several sheets if necessary) U.S. Department of Commerce Patent and Trademark Office	Docket No. **ALZA-0143**	Application No. **10/645,715**
	Applicant **George V. Guittard, et al.**	
	Filing Date **August 20, 2003**	Group **1614**
	Confirmation No. **8447**	

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
	11	ALZA Communication Exchange, A.C.E. Briefing, "The Making of Ditropan® XL: An Epic Celebrating the Cast of ALZAns who made it Happen, from 1993 to Today", **January 20, 1999,** DXL-063089 thru DXL-063100, **Defendant's Exhibit DX 00448,**
	12	Theeuwes, et al., "Elementary Osmotic Pump for Indomethacin", *Journal of Pharmaceutical Sciences,* **March 1983,** 72(3), 253-258, **Defendant's Exhibit DX 00450**
	12A	Thuroff, J.W. et al., "Randomized, Double-Blind, multicenter Trial on Treatment of Frequency, Urgency and Incontinence related to Detrusor Hyperactivity: Oxybutynin Versus Propantheline Versus Placebo", *The Journal of Urology,* **April 1991,** 145, 813-817, **Defendant's Exhibit DX 00453**
	13	Welling, P.G., "In Vitro Methods to Determine Bioavailability: In Vitro-In Vivo Correlations", 223 thru 232, **Defendant's Exhibits DX 00462**
	14	Executive Summary, OROS® (Oxybutynin Chloride) CPC-1, **October 1997,** DXL-031021 thru DXL-063202, **Defendant's Exhibit DX 01079**
	15	Stage 0: Product Concept Assessment Form Synopsis, **March 2, 1993,** DXL- 063198 thru 063202, **Defendant's Exhibits DX 01143**
	16	Ditropan Xl and Market Pricing, **Defendant's Exhibit DX 01151,** JJ-00447 thru JJ-00456
	17	Harry C. Boghician (Portfolio), 5 pages **Defendant's Exhibit DX 1216 A**
	18	In the United States District Court for the Northern District of West Virginia, ALZA Corporation, Plantiff v. Mylan Laboratories, Inc., Mylan Pharmaceuticals, Inc. Defendants, C.A. No:. 1:03CV61, Expert Report of James A. Forstner, **April 29, 2004, Defendant's Exhibit DX 01219**
	19	Curriculum Vitae-Gordon L. Amidon, **Defendant's Exhibit DX 01226,** 93 pages
	20	Fax Letter from Jeffrey I.D. Lewis to James H. Wallace, **Defendant's Exhibit DX 01245,** 2 pages
	21	Curriculum Vitae, Stanley Kandzari, M.D. **Updated April 1, 2005, Defendant's Exhibit DX 1266 B,** 1page
EXAMINER		**DATE CONSIDERED**

Form PTO-1449 Modified List of Patent and Publications Cited by Applicant (Use several sheets if necessary) U.S. Department of Commerce Patent and Trademark Office	Docket No. **ALZA-0143**	Application No. **10/645,715**
	Applicant **George V. Guittard, et al.**	
	Filing Date **August 20, 2003**	Group **1614**
	Confirmation No. **8447**	

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
	22	Experimental Formula Sheet-Sustained Release Oxybutynin Chloride Pellets, MYLAN 1014435, **Defendant's Exhibit DX 01403**
	23	Australia Patents Act, "Complete Specification for Sustained Release Pharmaceutical Composition, 55 pages
	24	Saks, S.R. MD, "Pharmacokinetics of OROS® and Oxybutynin", *ALZA Corporation Physician Advisory Board Meeting,* **October 9-11, 1998,** DXL-044580 thru 004591 **Defendant's Exhibit DX 1501**
	25	Winkler, H.A. et al., "Treatment of Detrusor Instability with Oxybutynin Rectal Suppositories" *International Urogynecology Journal,* **1998,** 9, 100-102, **Defendant's Exhibit DX 1503,** 3 pages
	26	Massad, C.A. et al., "The Pharmacokinetics of Intravesical and Oral Oxybutynin Chloride", *The Journal of Urology,* **1992,** 148, 595-597, **Defendant's Exhibit DX 1504**
	27	**Defendant's Exhibit DX 1507,** DXL084950 thru DXL084985
	28	Projected Ditropan Xl Net Trade Sales, **Defendant's Exhibit DX 1511,** 5 pages
	29	Quarterly TRX Market Share and TRX Following Launch(Quarterly), **Defendant's Exhibits DX 1512,**
	30	Gupta, S. PhD., "New Pharmacokinetic Information on Ditropan® XL, *Physician Advisory Board Meeting, Medical Education Technologies Job # AZ11-0013,* **Defendant's Exhibit DX 1515C,** DXL 045275 thru 045313
	31	Stage 0: Product Concept Assessment Form Synopsis, **March 2, 1993, Defendant's Exhibit DX 1517,** DXL 063216 thru 063222
EXAMINER		**DATE CONSIDERED**

Form PTO-1449 Modified List of Patent and Publications Cited by Applicant (Use several sheets if necessary) U.S. Department of Commerce Patent and Trademark Office	Docket No. **ALZA-0143**	Application No. **10/645,715**
	Applicant **George V. Guittard, et al.**	
	Filing Date **August 20, 2003**	Group **1614**
	Confirmation No. **8447**	

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
	32	Final Report C-96-074-02 "Effect of Food on the Pharmacokinetics and Bioavailability of OROS® (oxybutynin chloride) relative to Ditopan®", **November 1997,** DXL-081963 thru 081999, **Defendant's Exhibit DX 1530**
	33	Oxybutynin Chloride, **Defendant's Exhibit DX 1540,** DXL 050624 ,050505 thru 050516, 9 pages
	34	Oxybutynin Chlroide, **Defendant's Exhibit DX 1541,** DXL 050625, 1 page
	35	**Defendant's Exhibit DX 1542,** 1page
	36	**Defendant's Exhibit DX 1543,** ALZA Expert 00267, 1 page
	37	Genitourinary Smooth Muscle Relaxants, *American Hospital Formulary Service,* **1997, Defendant's Exhibit DX 1544,** DXL 079384 thru DXL 0793387
	38	Letter from Jeffrey I.D. Lewis to Nicholas A Peppas, Ph.D., **Defendant's Exhibits 1546,** 5 pages
	39	In the United States District Court for the Southern District of Florida, Pfizer, Inc. and Alza Corporation, Plaintiffs, v. Andrx Corporation, Andrx Pharmaceuticals, inc., and Andrx Pharmaceuticals, LLC, Defendants, C.A. No:. 01-8636, Amended Complaint, **Defendant's Exhibit DX 1548,** 17 pages
	40	Siepmann, J. et al., "HPMC-Matrices for Controlled Drug Delivery: A New Model Combining Diffusion, Swelling, and Dissolution Mechanisms and Predicting the Release Kinetics", *Pharmaceutical Research,* **1999,** 16(11), 1748-1756, **Defendant's Exhibit DX 1551**
	41	Siepman, J. et al., "A New Model Describing the Swelling and Drug Release Kinetics from Hydroxypropyl Methylcellulose Tablets", *Journal of Pharmaceutical Sciences,* **January 1999,** 88(1), 65 thru 72, **Defendant's Exhibit DX 1552**
EXAMINER		**DATE CONSIDERED**

Form PTO-1449 Modified List of Patent and Publications Cited by Applicant (Use several sheets if necessary) U.S. Department of Commerce Patent and Trademark Office	Docket No. **ALZA-0143**	Application No. **10/645,715**
	Applicant **George V. Guittard, et al.**	
	Filing Date **August 20, 2003**	Group **1614**
	Confirmation No. **8447**	

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
	42	Baker, R., "Controlled Release of Biologically Active Agents", **1987,** 1-21, **Defendant's Exhibit DX 1553**
	43	'355 Claim 1 vs. Baichwal Example 15 Data, 1 page, **Defendant's Exhibit 1554**
	44	'355 Claim 1 vs. Baichwal Example 15 vs. Example 1, 1 page, **Defendant's Exhibit 1557,**
	45	Fundamentals of Controlled Release and Pharmaceutical Engineering, **Spring 1993, Defendant's Exhibit DX 1558**
	46	'355 Claim 1 vs. '355 Example 1 Data, **Defendant's Exhibit DX 1559,** 1 page
	47	U.S. Pharmacopeia & National Formulary, **Defendant's Exhibit DX 1561,** 2232-2240
	48	Figure 1 of the '355 Patent: Typical Release Curve for 24-Hour Controlled Release Data, **Defendant's Exhibit DX 1562, 1563** 2 pages
	49	General Requirements for Tests and Assays, **Defendant's Exhibit DX 1566,** 1833 thru 1861
	49A	Moore, K. et al., "Oxybutynin Hydrochloride (3mg) in the Treatment of Women with Idiopathic Detrusor Instability", *British Journal of Urology,* **1990,** 66, 479-485, **Defendant's Exhibit DX 1570**
	50	USP Dissolution Calibrator, Non-Disintegrating Type, **Defendant's Exhibit DX 1573,** 2 pages
	51	Oxybutynin Chloride ER (OXYB-0262) Data, **Defendant's Exhibit DX 1580-DX 1586,** Mylan 0060307,1 page
EXAMINER		**DATE CONSIDERED**

Form PTO-1449 Modified List of Patent and Publications Cited by Applicant (Use several sheets if necessary) U.S. Department of Commerce Patent and Trademark Office	Docket No. **ALZA-0143**	Application No. **10/645,715**
	Applicant **George V. Guittard, et al.**	
	Filing Date **August 20, 2003**	Group **1614**
	Confirmation No. **8447**	

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
	52	Reviewer Guidance-Validation of Chromatographic Methods, *Center for Drug Evaluation and Research (CDER),* **November 1994,** 1 thru 30, **Defendant's Exhibit 1588**
	53	Drug Release Profile Data- **Defendant's Exhibit DX 1589,** MYLAN 1014490-1014492
	54	Drug Release Profile Data- **Defendant's Exhibit DX 1590,** MYLAN 1014485-1014487
	55	Drug Release Profile Data- **Defendant's Exhibit DX 1591,** MYLAN 1014477-1014479
	56	Drug Release Profile Data- **Defendant's Exhibit DX 1592,** MYLAN 1014480-1014482
	57	ALZA Corporation-Payments to Virginia Commonwealth University Data-**Defendant's Exhibit 1593,** DXL 085000-085017
	58	Mylan 10 mg Product-Apparatus 2(Paddle) with Media Switch Data-**Defendant's Exhibit DX 1594-1598**
	59	U.S. Pharmacopeia & National Formulary, **Defendant's Exhibit DX 1803,** 1128-1129
	60	Baichwal Teaches the Conventional Wisdom Data-**Defendant's Exhibit DX 1804,** 1 page
	61	Mylan 5mg Product Data-**Defendant's Exhibit DX 1805,** 7 pages

EXAMINER	**DATE CONSIDERED**

Form PTO-1449 Modified List of Patent and Publications Cited by Applicant (Use several sheets if necessary) U.S. Department of Commerce Patent and Trademark Office	Docket No. **ALZA-0143**	Application No. **10/645,715**
	Applicant **George V. Guittard, et al.**	
	Filing Date **August 20, 2003**	Group **1614**
	Confirmation No. **8447**	

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
	62	Mylan 10 mg Product Data-**Defendant's Exhibit DX 1806,** 4 pages
	63	Concentration Result Data-**Defendant's Exhibit DX 1808,** 1 page
	64	U.S. Pharmacopeia- The Official Compendia of Standards, **Defendant's Exhibit 1814,** 4 pages
	65	Mylan 10 mg Product, Mylan 5 mg Product Data- **Defendant's Exhibit DX 1816-1817**
	66	U.S. Pharmacopeia- The Official Compendia of Standards, **Defendant's Exhibit 1818,** 6-8, 2160-2165
	67	Mylan 10 mg Product Data- **Defendant's Exhibit DX 1819,** 1 page
	68	U.S. Pharmacopeia- The Official Compendia of Standards, **Defendant's Exhibit 1821,** 2513-2519
	69	Copy of CD- **Defendant's Exhibit DX 1822**
	70	'355 Claim 1 vs. Examples A and B Data- **Defendant's Exhibit 1823,** 1 page
	71	Data- **Defendant's Exhibit 1825,** 1 page
EXAMINER		**DATE CONSIDERED**

Form PTO-1449 Modified List of Patent and Publications Cited by Applicant (Use several sheets if necessary) U.S. Department of Commerce Patent and Trademark Office	Docket No. **ALZA-0143**	Application No. **10/645,715**
	Applicant **George V. Guittard, et al.**	
	Filing Date **August 20, 2003**	Group **1614**
	Confirmation No. **8447**	

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
	72	Mylan Tablet Data-**Defendant Exhibits 1827 thru 1831**
	73	5 mg Oral Solution Data-**Defendant's Exhibit 1832-1833,** 46 pages
	74	Mylan Tablet Data-**Defendant's Exhibit 1836,** 1 page
	75	Mylan Tablet Data-**Defendant's Exhibit 1900-1901**
	76	Miyamoto, E. et al., "Physico-Chemical Properties of Oxybutynin", *Analysts,* **July 1994,** 119, 1489-1492, **Defendant's Exhibit 1902,** DXL 005871-005874
	77	State of the Art: Colonic Absorption Studies, Defendant's Exhibit DX 2001, 1 page
	78	Colonic Absorption Studies and Data-**Defendant's Exhibit DX 2002**
	79	Wong, P.S.L. et al., "Osmotically Controlled Tablets", *Modified-Release Drug Delivery Technology,* **2003,** 101-114 **Joint Exhibit 109**
	80	ALZA: OROS® Oral Delivery Technology, **March 9, 2004,** http://www.alza.com/print/oros, **Joint Exhibit 111,** 2 pages
	81	Patent Information: DITROPAN XL®(oxybutynin chloride) Extended Release Tablet, **Joint Exhibit 112,** DXL 070943
EXAMINER		**DATE CONSIDERED**

Form PTO-1449 Modified List of Patent and Publications Cited by Applicant (Use several sheets if necessary) U.S. Department of Commerce Patent and Trademark Office	Docket No. **ALZA-0143**	Application No. **10/645,715**
	Applicant **George V. Guittard, et al.**	
	Filing Date **August 20, 2003**	Group **1614**
	Confirmation No. **8447**	

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
	82	Douchamps, J. et al., "The Pharmacokinetics of Oxybutynin in Man", *Eur J. Clin Pharmacol,* **1988,** 35, 515-520, **Joint Exhibit 116,** 5 pages
	83	Cystrin® SR, Sustained Release Oxybutynin Hydrochloride, Development Pharmaceutics, **March 9, 1994,** PW 000225-PW 000280, **Joint Exhibit 130**
	84	Patent Data, DXL 070941-070942, **Joint Exhibit 131**
	85	The United States Pharmacopeia Convention, Inc. **1990,** 1790-1799, **Joint Exhibit 133**
	86	Oxybutynin/Official Monographs, **Joint Exhibit 134,** 1 page
	87	The United States Pharmacopeia Convention, Inc., The Official Compendia of Standards, **2002,** 2010-2022, **Joint Exhibit 135**
	88	**Joint Exhibit 137,** 1578-1581
	89	Van Bommel, E.M.G. et al., "Comparison of *In Vitro and In Vivo* Release Characteristics of Acetaminophen from Gradient Matrix Systems, *Biopharmaceutics & Drug Disposition,* 1991, 12, 367-373, **Joint Exhibit 139**
	90	Oxybutynin Chloride Extended-Release Tablets, 10 MG, Uniformity of Dosage Units (FP-OXYB10-CU-M) , 5514-5539, MYLAN 0065620-0065646, **Joint Exhibit 232**
	91	Preik, M. et al., "Effect of Controlled-Release Delivery on the Pharmacokinetics of Oxybutynin at Different Dosages: Severity-Dependent Treatment of the Overactive Bladder", *BJU International,* 2004, 821-827, **Plaintiff's Exhibit 396**
EXAMINER		**DATE CONSIDERED**

Form PTO-1449 Modified List of Patent and Publications Cited by Applicant (Use several sheets if necessary) U.S. Department of Commerce Patent and Trademark Office	Docket No. **ALZA-0143**	Application No. **10/645,715**
	Applicant **George V. Guittard, et al.**	
	Filing Date **August 20, 2003**	Group **1614**
	Confirmation No. **8447**	

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
	92	Patent Data, **Plaintiff's Exhibit 40, 43, 53, 54, 58, 59**, 1 page each, 6 total pages
	93	Leesman, G.D. et al., "Simulation of Oral Drug Absorption: Gastric Emptying and Gastointestinal Motility", *Pharmacokinetics,* Chapter 6, 267-284, **Plaintiff's Exhibit 131**
	94	Patent Data, **Plaintiff's Exhibit 143**, 1 page
	95	Product Monograph, "Once-a-Day Ditropan® XL, **Plaintiff's Exhibits 157**, DXl-044976 thru DXL-045027
	96	Anderson, R.U. et al., "Once Daily Controlled Versus Immediate Release Oxybutynin Chloride for Urge Urinary Incontinence", *The Journal of Urology,* **June 1999,** 161, 1809-1812, **Plaintiff's Exhibit 197**
	97	Versi, E. MD, PhD. Et al., "Dry Mouth with Conventional and Controlled Release Oxybutynin in Urinary Incontinence", *Obstetrics & Gynecology,* **2000**, 95(5), 718-721, **Plaintiff's Exhibit 198**
	98	Appell, R.A. MD. et al., "Prospective Randomized Controlled Trial of Extended-Release Oxybutynin Chloride and Tolterodine Tartrate in the Treatment of Overactive Bladder: Results of the OBJECT Study", *May Clin. Proc.,* **2001**, 76, 358-363, **Plaintiff's Exhibit 199**
	99	OROS TDC-1 Meeting Minutes, **November 23, 1993,** DXL-027199-02713, **Plaintiff's Exhibit 203**
	100	Cystrin Cr-Release Rate Profile, **August 14, 1998,** DXL-017224-017225, **Plaintiff's Exhibit 213**
	101	Patent Data-DXL 016934, **Plaintiff's Exhibit 260**
EXAMINER		DATE CONSIDERED

Form PTO-1449 Modified List of Patent and Publications Cited by Applicant (Use several sheets if necessary) U.S. Department of Commerce Patent and Trademark Office	Docket No. **ALZA-0143**	Application No. **10/645,715**
	Applicant **George V. Guittard, et al.**	
	Filing Date **August 20, 2003**	Group **1614**
	Confirmation No. **8447**	

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
	102	Gupta, S.K. PhD. et al., "Pharmacokinetics of an Oral Once-a-Day Controlled-Release Oxybutynin Formulation Compared with Immediate-Release Oxybutynin", *J. Clin. Pharmacol,* **1999,** 39, 289-296, DXL-023945-023952, **Plaintiff's Exhibit 261**
	103	Patent Data, MYLAN 1008193-1008196, **Plaintiff's Exhibit 266**
	104	Highlights of OROS TDC-1 Meeting, **June 28, 1993,** DXL 017162, **Plainitff's Exhibit 287**
	105	OROS TDC-1 Meeting Minutes-**September 17, 1993,** DXL 027224-027236, **Plaintiff's Exhibit 288**
	106	Work Plan and Cost Estimate for Stage 2 Activities for OROS® Oxybutynlin, DXL 043711-043715, **Plaintiff's Exhibit 289**
	107	Commercial Assessment OROS/TTS TDC-1 Oxybutynin, Stage 3, **September 1995,** DXL 063416-063563, **Plaintiff's Exhibit 308**
	108	OROS TDC-1 Meeting Minutes, **October 21, 1993,** DXL 027214-027215, **Plaintiff's Exhibit 309**
	109	Sathyan, G. et al., "Effect of OROS® Controlled-Release Delivery on the Pharmacokinetics and Pharmacodynamics of Oxybutynin Chloride", *J. Clin. Pharmacol,* **2001,** 52, 409-417, DXL 051995-052003, **Plaintiff's Exhibit 315**
	110	Buyse, G. et al., "Intravesical Pxybutynin for Neurogenic Bladder Dysfunction: Less Systemic Side Effects Due to Reduced First Pass Metabolism", *The Journal of Urology,* **1998,** 160, 892-896, **Plaintiff's Exhibit 323**
	111	Diokno, A.C. et al., "Prospective, Randomized, Double-blind Study of the Efficacy and Tolerability of the Extended-Release Formulations of Oxybutynin and Tolterodine for Overactive Bladder: Results of the OPERA Trail", *Mayo Clin Proc.,* **2003,** 78, 687-695, **Plaintiff Exhibit 326**
EXAMINER		DATE CONSIDERED

Form PTO-1449 Modified List of Patent and Publications Cited by Applicant (Use several sheets if necessary) U.S. Department of Commerce Patent and Trademark Office	Docket No. **ALZA-0143**	Application No. **10/645,715**
	Applicant **George V. Guittard, et al.**	
	Filing Date **August 20, 2003**	Group **1614**
	Confirmation No. **8447**	

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

	112	Gupta, P. K. et al., "Oral Controlled-Release Delivery", *Treatise on Controlled Drug Delivery,* **1992,** PX329_0002-329_0058, **Plaintiff's Exhibit 329**
	113	Dmochowski, R.R. et al., "Advancements in Pharmacologic Management of the Overactive Bladder", *Urology,* **2000,** 54(6A), 41-49, **Plaintiff's Exhibit 391**
	114	Read, N.W. et al., "Gastrointestinal Dynamics and Pharmacology for the Optimum Design of Controlled-Release Oral Dosage Forms", *CRC Critical Reviews in Therapeutic Drug Carrier Systems,* **1987,** 4(3), 221-263, **Plaintiff's Exhibits 397**
	115	Miyamoto, E. et al., "Physico-Chemical Properties of Oxybutynin", *Analyst,* **1994,** 119, 1489-1492, DXL 005871-005874
	116	Modern Pharmaceutics, Oral Drug Delivery, Chapter 5, ALZA Research Library, DXL 043878 thru DXL 043926, **Plaintiff's Exhibit 403**
	117	Physicians' Desk Reference®, PDR®, 47th Edition, **1993,** 1377-1378, DXL 028121-DXL 028123, **Plaintiff's Exhibit 451**
	118	Longer, M.A. et al., "Sustained-Release Drug Delivery Systems", *Pharmaceutical Sciences,* **1985,** 92, 1644-1661, **Plaintiff's Exhibit 462**
	119	Patent Data, JJ 00142 thru JJ 00281, **Plaintiff's Exhibit 464**
	120	Banker, G.S., "Pharmaceutical Applications of Controlled Release: An Overview of the Past, Present, and Future", *Medical Applications of Controlled Release,* **1984,** Volume II, 1-34, **Plaintiff's Exhibit 467**
	121	Yu, L.X. et al., "Transport Approaches to the Biopharmaceutical Design of Oral Drug Delivery Systems: Prediction of Intestinal Absorption", *Advanced Drug Delivery Reviews,* **1996,** 19, 359-376, **Plaintiff's Exhibit 471**

EXAMINER	DATE CONSIDERED

Form PTO-1449 Modified List of Patent and Publications Cited by Applicant (Use several sheets if necessary) U.S. Department of Commerce Patent and Trademark Office	Docket No. **ALZA-0143**	Application No. **10/645,715**
	Applicant **George V. Guittard, et al.**	
	Filing Date **August 20, 2003**	Group **1614**
	Confirmation No. **8447**	

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
	122	Lipka, E. et al., "Setting Bioequivalence Requirements fro Drug Development based on Preclinical Data: Optimizing Oral Drug Delivery Systems", *Journal of Controlled Release,* **1999,** 62, 41-49, **Plaintiff's Exhibit 473**
	123	Lukkari, E. et al., "Effect of Food on the Bioavailability of Oxybutynin from a Controlled Release Tablet", *Eur. J. Clin. Pharmacol.,* **1996,** 50, 221-223, **Plaintiff's Exhibit 482**
	124	Rocca, J. G. PhD. et al., "Oral Drug Delivery: Prospects & Challenges", *Drug Delivery Technology,* **2004,** 4(4), 53-57, **Plaintiff's Exhibit 484**
	125	Waldeck, K. et al., "Comparison of Oxybutynin and its Active Metabolite, N-Desethyl-Oxybutynin, in the Human Detrusor and Parotid Gland", *The Journal of Urology,* **1997,** 157, 1093-1097, **Plaintiff's Exhibit 486**
	126	Chancellor, M.B. Md, et al., "A Comparison of the Effects on Saliva Output of Oxybutynin Chloride and Tolterodine Tartrate", *Clinical Therapeutics,* **2001,** 23(5), 753-760, **Plaintiff's Exhibit 488**
	127	Laboratory Notebook, Biomaterials & Drug Delivery Labs, **Plaintiff's Exhibit 491**
	128	Patent Data-**Plaintiff's Exhibit 494 (d)**
	129	Patent Data-**Plaintiff's Exhibit 495 (e)**
	130	Patent Data-**Plaintiff's Exhibit 496 (f)**
	131	Patent Data-**Plaintiff's Exhibit 497 (g)**

EXAMINER	DATE CONSIDERED

Form PTO-1449 Modified List of Patent and Publications Cited by Applicant (Use several sheets if necessary) U.S. Department of Commerce Patent and Trademark Office	Docket No. **ALZA-0143**	Application No. **10/645,715**
	Applicant **George V. Guittard, et al.**	
	Filing Date **August 20, 2003**	Group **1614**
	Confirmation No. **8447**	

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
	132	Alza Corporation v. Mylan Laboratories, Inc. and Mylan Pharmaceuticals, Inc, No: 1:03cv61-Supplemental Expert Report of Anthony Lowman, Lowman Video, **Plaintiff's Exhibit 498 (h),** 1 page copy of the disc only
	133	Stage 0: Product Concept Assessment Form Synopsis, **March 2, 1993,** DXL- 016939 thru 016948, **Plaintiff's Exhibit 503**
	134	Translation of Finnish Package Insert (from Swedish language), DXL 012241-012243, **Plaintiff's Exhibit 506**
	135	Patent Data- JJ 02815 thru JJ 02817, **Plaintiff's Exhibit 536, 538**
	136	Patent Data- **Plaintiff's Exhibit 548, 549, 550, 551**
	137	Curriculum Vitae of Nicholas A. Peppas, 1- 113, **Plaintiff's Exhibit 552,**
	138	General Information- In Vitro and In Vivo Evaluation, *The United States Pharmacopeia Convention, Inc.,* 2161, **Plaintiff's Exhibit 554**
	139	Patent Data-Drug Release Profile-**Plaintiff's Exhibit 555,** MYLAN 1014477-1014492
	140	Curriculum Vitae of Anthony M. Lowman, Ph.D., 15 pages, **Plaintiff's Exhibit 556**
	141	Chancellor, M.B. et al., "Spit Study to Compare Different Formulations of Oxybutynin", Accepted as Poster Presentation at 1999 AUA, **Plaintiff's Exhibit 561,** DXL 048067, **Plaintiff's Exhibit 561**
EXAMINER		DATE CONSIDERED

Form PTO-1449 Modified List of Patent and Publications Cited by Applicant (Use several sheets if necessary) U.S. Department of Commerce Patent and Trademark Office	Docket No. **ALZA-0143**	Application No. **10/645,715**
	Applicant **George V. Guittard, et al.**	
	Filing Date **August 20, 2003**	Group **1614**
	Confirmation No. **8447**	

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
	142	Gittleman, M. et al., "Once-Daily Oxybutynin Chloride (Ditropan XL) in Patients on other Anticholinergic Medications", Accepted as Poster Presentation at 1999 AUA, **Plaintiff's Exhibit 562,** DXL 048068
	143	Sand, P. Md. et al., "Dose Titration with Once-Daily Oxybutynin Chloride (Ditropan XL) in Previously Treated and Naïve Patients", Accepted as Oral Presentation at 1999 ACOG, **Plaintiff's Exhibit 563,** DXL 048071
	144	Versi, E. Md. et al., "Improving Urge Incontinence Treatments by Decreasing Dry Mouth with Controlled-Release Oxybutynin (Ditropan XL), Accepted as Poster Presentation at 1999 ACOG, **Plaintiff's Exhibit 566,** DXL 048072
	145	Schmidt, R.A., "Efficacy of Controlled-Release Once-a-Day Oxybutynin Chloride for Urge Urinary Incontinence", *Division of Urology,* **Plaintiff's Exhibit 567,** DXL 048073
	146	Brown, J., "Comparison of tolerability and Efficacy of Once-a-Day vs. Immediate-Release Oxybutynin Chloride in Patients with Urge Urinary Incontinence", **1998, Plaintiff's Exhibit 569,** DXL 048078
	147	Michel, M.C., "A Benefit-Risk Assessment of Extended-Release Oxybutynin" *Drug Safety,* **2002,** 25(12), 867-876, **Plaintiff's Exhibit 570**
	148	Physicians' Desk Reference®, **1994,** 48 edition, 20, **Plaintiff's Exhibit 577**
	149	Oxybutynin Chloride Extended Release Tablets 10 mg, Finished Product Specifications, MYLAN 0046025-0046026, **Plaintiff's Exhibit 579**
	150	Patent Data-MYLAN 1006248-1006257, **Plaintiff's Exhibit 591**
	151	Patent Data- **Plaintiff's Exhibit 592, 593, 594, 595**

EXAMINER	DATE CONSIDERED

Form PTO-1449 Modified List of Patent and Publications Cited by Applicant (Use several sheets if necessary) U.S. Department of Commerce Patent and Trademark Office	Docket No. **ALZA-0143**	Application No. **10/645,715**
	Applicant **George V. Guittard, et al.**	
	Filing Date **August 20, 2003**	Group **1614**
	Confirmation No. **8447**	

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
	152	Patent Data-Experimental Formula Sheet- MYLAN 1014435-1014466, **Plaintiff's Exhibit 596**
	153	Qureshi, S.A. et al., "Typical Variability in Drug Dissolution Testing: Study with USP and FDA Calibrator Tablets and a Marketed Drug (Glibenclamide) Product", *European Journal of Pharmaceutical Sciences,* **1999,** 7, 249-258, **Plaintiff's Exhibits 598**
	154	Patent Data- **Plaintiff's Exhibit 602 thru 649**
	155	Curriculum Vitae- Michael B. Chancellor, M.D., 83 pages, **Plaintiff's Exhibit 650**
	156	Goldenberg, M.M. PhD. "An Extended Release Formulation of Oxybutynin Chloride for the Treatment of Overactive Urinary Bladder", *Clinical Therapeutics,* **1999,** 21(4), 634-642, DXL 052302-052031, **Defendant's Exhibit 656**
	157	Ouslander, J.G. MD., "Management of Overactive Bladder", *The New England Journal of Medicine,* **2004,** 350, 786-799, **Plaintiff's Exhibit 664**
	159	Abrahamsson, B. et al., "Absorption, Gastrointestinal Transit, and Tablet Erosion of Felodipine Extended-Release (ER) Tablets", *Pharmaceutical research,* **1993,** 10(5), 709-714
	160	Artursson, P., "Epithelial Transport of Drugs in Cell Culture. I: A Model for Studying the Passive Diffusion of Drugs over Intestinal Absorptive (Caco-2) Cells", *Journal of Pharmaceutical Sciences,* **June 1990,** 79(6), 476-482
	161	Chao, S.T. et al., "Effect of Food on Bioavailability of Pseudoephedrine and Brompheniramine Administered from a Gastrointestinal Therapeutic System", *Journal of Pharmaceutical Sciences,* **1991,** 80(5), 432-435
EXAMINER		DATE CONSIDERED

Form PTO-1449 Modified List of Patent and Publications Cited by Applicant (Use several sheets if necessary) U.S. Department of Commerce Patent and Trademark Office	Docket No. **ALZA-0143**	Application No. **10/645,715**
	Applicant **George V. Guittard, et al.**	
	Filing Date **August 20, 2003**	Group **1614**
	Confirmation No. **8447**	

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
	162	Chung, M. PhD. et al. "Clinical Pharmacokinetics of Nifedipine Gastrointestinal Therapeutic System", *The American Journal of Medicine,* **1987,** 83, 10-14
	163	Davis, S.S. et al., "Relationship between the rate of Appearance of Oxprenolol in the Systemic Circulation and the Location of an Oxprenolol Oros 16/260 Drug Delivery System within the Gastrointestinal Tract as Determined by Scintigraphy", *Br. J. Clin. Pharmac,* **1988,** 26, 435-443
	164	Harder, S. et al., "Ciprofloxacin Absorption in Different Regions of the Human Gastrointestinal Tract. Investigations with the hf-Capsule", *Br. J. Clin. Pharmac.,* **1990,** 30, 35-39
	165	Hirtz, J., "The Absorption Window; Fact or Fiction?", *Pharmacy International,* **1984,** 175-178
	166	Marathe, P.H. et al., "Absorption and Presystemic Metabolism of Nefazodone Administered at Different Regions in the Gastrointestinal Tract of Humans", *Pharmaceutical Research,* **1995,** 12(11), 1716-1721
	167	Riley, S.A. et al., "Absorption of Polar Drugs following Caecal Instillation in Healthy Volunteers", *Aliment Pharmacol Ther.,* **1992,** 6, 701-706
	168	Sandberg, A. et al., "Steady-State Bioavailability and Day-to-Day Variability of a Multiple-Unit (CR/ZOK) and a Single-Unit (OROS) delivery System of Metoprolol after Once-Daily Dosing", *Pharmaceutical Research,* **1993,** 10(1), 28-34
	169	Stiehl, A. et al., "Colonic Absorption of Ursodeoxycholic Acid in Man", 42, 323-325
	170	Wilding, I.R. et al., "Gastrointestinal Transit and Systemic Absorption of Captopril from a Pulsed-Release Formulation", *Pharmaceutical Research,* **1992,** 9(5), 654-657
	171	Williams, M.F. et al., "Influence of Gastrointestinal Site of Drug Delivery on the Absorption Characteristics of Ranitidine", *Pharmaceutical Research,* **1992,** 9(9), 1190-1194
EXAMINER		DATE CONSIDERED

Form PTO-1449 Modified List of Patent and Publications Cited by Applicant (Use several sheets if necessary) U.S. Department of Commerce Patent and Trademark Office	Docket No. **ALZA-0143**	Application No. **10/645,715**
	Applicant **George V. Guittard, et al.**	
	Filing Date **August 20, 2003**	Group **1614**
	Confirmation No. **8447**	

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
	172	Wilson, C.G. et al., "Bimodal release of Ibuprofen in a Sustained-Release Formulation: A Scintigraphic and Pharmacokinetic Open Study in Healthy Volunteers under Different Conditions of Food Intake", *International Journal of Pharmaceutics,* **1989,** 50, 155-161
	173	Antonin, K-H., "Other Methods in Studying Colonic Drug Absorption", Chapter 5, 89-107
	174	Antonin, K.H. et al., "Evaluation of the Colonic Drug Absorption in Patients with an Artificial Intestinal Stoma and by Colonoscopy in Normal Volunteers", *National Library of Medicine,* 39-52
	175	Bieck, P.R., "Drug Absorption from the Human Colon", *Acta Pharm Technol,* **1987,** 33, 109-114
	176	Davis, S.S., "Assessment of Gastrointestinal Transit and Drug Absorption", *Drug Delivery and its Therapeutic Application,* **1989,** 9, 89-101
	177	Hirtz, J., "Intubation Techniques for the Study of the Absorption of Drugs in Man", *National Library of Medicine,* 3-12
	178	Hirtz, J., "The Gastrointestinal Absorption of Drugs in Man: A Review of Current Concepts and Methods of Investigation", *Br. J. Clin. Pharmac,* **1985,** 19, 77S-83S
	179	Schuster, O. et al., "Course of Development of the HF-Capsule-Variations and Method-Related Typical Findings", *National Library of Medicine,* 28-38
	180	Colonic Absorption Review Articles, **Defendant's Exhibit DX 2003,** 1 page
	181	Fara, J.W., "Colonic Drug Absorption and Metabolism", *Novel Drug Delivery and its Therapeutic Application,* **1989,** 10, 103-112, **Defendant's Exhibit DX 2004**
EXAMINER		DATE CONSIDERED

Form PTO-1449 Modified List of Patent and Publications Cited by Applicant (Use several sheets if necessary) U.S. Department of Commerce Patent and Trademark Office	Docket No. **ALZA-0143**	Application No. **10/645,715**
	Applicant **George V. Guittard, et al.**	
	Filing Date **August 20, 2003**	Group **1614**
	Confirmation No. **8447**	

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
	182	Summary of Dr. Dmochowski's ALZA Contracts, **Defendant's Exhibit DX 2005**
	183	Summary of Dr. Chancellor Contracts, **Defendant's Exhibit DX 2006**
	184	Alza Total Payments to Dr. Chancellor, **Defendant's Exhibit DX 2007 and DX 2007 A**
	185	Articles Regarding First-Pass Metabolisms, **Defendant's Exhibit DX 2008,** 1 page
	186	Articles Regarding Reduced Side Effects from Non-Oral Administration, **Defendant's Exhibit DX 2009,** 1 page
	187	Aaltonen, L. et al., "Antimuscarinic Activity of Oxybutynin in the Human Plasma Quantitated by a Radioreceptor Assay", *Acta Pharmacol. Et Toxicol,* **1984,** 55, 100-103
	188	Hughes, K.M. et al., "Measurement of Oxybutynin and its N-Desethyl Metabolite in Plasma and its Application to Pharmacokinetic Studies in Young, Elderly and Frail Elderly Volunteers", *Xenobiotica,* **1992,** 22(7), 859-869
	189	Abstracts of the 1st Congress of the European Association for Clinical Pharmacology and Therapeutics, **1995,** *Thérapie,* 65-68, **Plaintiff's Exhibit 485**
	190	Madersbacher, H. Md. et al, "Control of Detrusor Hyperreflexia by the Intravesical Instillation of Oxybutynine Hydrochloride", *Paraplegia,* **1991,** 29, 84-90
	191	Ditropian Xl, Prescribing Information, **Joint Exhibit 239,** 2 pages

EXAMINER	DATE CONSIDERED

Form PTO-1449 Modified List of Patent and Publications Cited by Applicant (Use several sheets if necessary) U.S. Department of Commerce Patent and Trademark Office	Docket No. **ALZA-0143**	Application No. **10/645,715**
	Applicant **George V. Guittard, et al.**	
	Filing Date **August 20, 2003**	Group **1614**
	Confirmation No. **8447**	

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
	192	OROS Oxybutynin Release Rates Patent Data-**Joint Exhibit 27**
	193	OROS Oxybutynin Release Rates Patent Data-**Joint Exhibit 28**
	194	OROS Oxybutynin Release Rates Patent Data Patent Data-**Joint Exhibit 29**
	195	OROS Oxybutynin Release Rates Patent Data Patent Data-**Joint Exhibit 30**
	196	OROS Oxybutynin Release Rates Patent Data Patent Data-**Joint Exhibit 31**
	197	OROS Oxybutynin Release Rates Patent Data Patent Data-**Joint Exhibit 32**
	198	OROS Oxybutynin Release Rates Patent Data Patent Data-**Joint Exhibit 33**
	199	OROS Oxybutynin Release Rates Patent Data Patent Data-**Joint Exhibit 35**
	200	Appendix D-List of Documents Reviewed-**Joint Exhibit 47**
	201	Alza Corp. v. Mylan, C.A. # 1:03CV61, Expert Report of Dr. Gordon Amidon, Appendix J: Photo of Different Dosage Forms CD, **Joint Exhibit 53**
EXAMINER		DATE CONSIDERED

Form PTO-1449 Modified List of Patent and Publications Cited by Applicant (Use several sheets if necessary) U.S. Department of Commerce Patent and Trademark Office	Docket No. **ALZA-0143**	Application No. **10/645,715**
	Applicant **George V. Guittard, et al.**	
	Filing Date **August 20, 2003**	Group **1614**
	Confirmation No. **8447**	

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
	202	Lish, P.M., "Oxybutynin-A Musculotropic Antispasmodic Drug with Moderate Anticholinergic Action", *Mead Johnson Research Center,* **1964,** 467-488, DXL 014384-014406, **Joint Exhibit 54**
	203	Experimental Formula Sheet Patent Data- MYLAN 1014326-1014370, **Joint Exhibit 55**
	204	Declaration of Dr. William Barr, **Joint Exhibit 56,** 7 pages
	205	Declaration of Dr. Patrick S.L. Wong, **Joint Exhibit 57,** 14 pages
	206	Draft Annotated Physician Insert-DITROPAN® XL, DXL 072395-DXL 072407, **Joint Exhibit 78**
	207	Rovner, E.S., et al., "Once-Daily, Extended-Release Formulations of Antimuscarinic Agents in the Treatment of Overactive Bladder: A Review", *European Urology,* **2002,** 41, 6-14, **Joint Exhibit 84**
	208	Guidance for Industry, Extended Release Oral Dosage Forms: Development, Evaluation, and Application of In/Vitro/In Vivo Correlations, *U.S. Dept. of Health and Human Services Food and Drug Administration Center for Drug Evaluation and Research,* **September 1997,** 1-24, **Joint Exhibit 86**
	209	Pitsiu, M. et al., "A Semiparametric Deconvolution Model to Establish in Vivo-In Vitro Correlation Applied to OROS Oxybutynin", *Journal of Pharmaceutical Sciences,* **2001,** 90(6), 702-712, **Joint Exhibit 89**
	210	Barr Affidavit, 1-23, **Joint Exhibit 90**
	211	Letter from S. Wayne Talton to Gary J. Buehler, re: Oxybutynin Chloride Extended-Release Tablets, 10mg and 76-644 Response to Agency Correspondence dated December 8, 2003, MYLAN 0978814-097835 w attached patent data, **Joint Exhibit 91**
EXAMINER		DATE CONSIDERED

Form PTO-1449 Modified List of Patent and Publications Cited by Applicant (Use several sheets if necessary) U.S. Department of Commerce Patent and Trademark Office	Docket No. **ALZA-0143**	Application No. **10/645,715**
	Applicant **George V. Guittard, et al.**	
	Filing Date **August 20, 2003**	Group **1614**
	Confirmation No. **8447**	

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
	212	Theeuwes, F., "Evolution and Design of Rate Controlled Osmotic Forms", *Current Medical Research and Opinion,* **1983,** 8(2), 20-27, **Joint Exhibit 93**
	213	Theeuwes, F., et al. "Systems for Triggered, Pulsed, and Programmed Drug Delivery", *Annals New York Academy of Science,* 428-440, **Joint Exhibit 94**
	214	Peters, K.M. et al., "Urinary Incontinence", 685-688, **Joint Exhibit 95**
	215	Yarker, Y.E. et al., "Oxybutynin-A review of its Pharmacodynamic and Pharmacokinetic Properties, and its Therapeutic Use in Detrusor Instability", *Drug and Aging,* **1993,** 3, 243-262, **Joint Exhibit 96**
	215A	Hughes, K.M. et al., "Measurement of Oxybutynin and its *N*-Desethyl Metabolite in Plasma, and its Application to Pharmacokinetic Studies in Young, Elderly and Frail Elderly Volunteers", *Xenobiotica,* **1992,** 22(7), 859-869, **Joint Exhibit 97**
	216	Robinson, T.G. et al., "Drugs in Focus: Oxybutynin Hydrochloride", *Prescribers' Journal,* **1994,** 34(1), 27-31, **Joint Exhibit 98**
	217	Katori, N. et al., "Estimation of Agitation Intensity in the GI Tract in Humans and Dogs Based on *in Vitro/in Vivo* Correlation", *Pharmaceutical Research,* **1995,** 12(2), 237-243, **Joint Exhibit 99**
	218	Lukkari, E. et al., "Effect of Time Interval between Food and Drug Ingestion on the Absorption of Oxybutynin from a Controlled-Release Tablet", *Pharmacology & Toxicology,* **1997,** 81, 31-34, DXL 005964-005967 **Joint Exhibit 101**
	219	Declaration of Dr. Patrick S.L. Wong, **Joint Exhibit 107,** 28 pages
	220	Declaration of Dr. William Barr, **Joint Exhibit 108**
	221	Patent Data-Ditropan XL 2003 OE/2004BP/2005 Forecast, JJ 00497-00577, **Plaintiff's Exhibit 139**
EXAMINER		DATE CONSIDERED

Form PTO-1449 Modified List of Patent and Publications Cited by Applicant (Use several sheets if necessary) U.S. Department of Commerce Patent and Trademark Office	Docket No. **ALZA-0143**	Application No. **10/645,715**
	Applicant **George V. Guittard, et al.**	
	Filing Date **August 20, 2003**	Group **1614**
	Confirmation No. **8447**	

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
	222	Collas, D. et al., "The Pharmacokinetic Properties of Rectal Oxybutynin- a Possible Alternative to Intravesical Administration", *Neurourology and Urodynamics,* **1997,** 16(5), 346-347
	223	Madersbacher, M. et al., "Intravesical Application of Oxybutynine: Mode of Action in Controlling Detrusor-Hyperreflexia", *Dept. Urology, Univ. Hosp. Innsbruck and Rehab Center,* 375-376
	224	Mizunaga, M, Md. et al., "Intravesical Instillation of Oxybutynin Hydrochloride Therapy for Patients with a Neuropathic Bladder", *Paraplegia,* **1994,** 32, 25-29
	225	Weese, D.L. et al., "Intravesical Oxybutynin Chloride: Experience with 42 Patients", *Urology,* **June 1993,** 41(6), 527-530
	226	O'Flynn, K.J. et al., "Intravesical Instillation of Oxybutynin Hydrochloride for Detrusor Hyper-Reflexia", *British Journal of Urology,* **1993,** 72, 566-570
	227	Remington's Pharmaceutical Sciences, "Pharmacokinetic Models", 36, 726
	228	Lukkari, E., "Clinical Pharmacology of Oxybutynin, with Special Reference to Pharmacokinetics and Interactions", *Department of Clinical Pharmacology,* **1997,** 1-50, **PW 000281-000331**
	229	Nilsson, C.G. et al. "Comparison of a 10-mg Controlled Release Oxybutynin Tablet with a 5-mg Oxybutynin Tablet in Urge Incontinent Patients", *Neurourology and Urodynamics,* **1997,** 16, 533-542, DXL 012130-012139
	230	"Cystrin CR Launched in Finland for Urinary Incontinence", *Doctor's Guide to Medical & Other News,* http://www.pslgroup.com, **May 7, 1998,** 2 pages
	231	Fincher, J.H., "Particle Size of Drugs and its relationship to Absorption and Activity", *J. Pharm. Sci.,* **1968,**57,1825-1835
EXAMINER		DATE CONSIDERED

Form PTO-1449 Modified List of Patent and Publications Cited by Applicant (Use several sheets if necessary) U.S. Department of Commerce Patent and Trademark Office	Docket No. **ALZA-0143**	Application No. **10/645,715**
	Applicant **George V. Guittard, et al.**	
	Filing Date **August 20, 2003**	Group **1614**
	Confirmation No. **8447**	

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
	232	King, R.E. PhD. et al., "Oral Solid Dosage Forms", *Pharm. Sci. by Remington*, 17th Ed., Ch. 90, pp. 1603-1625 **(1985)**, published by Mack Publishing
	233	Linhardt, R.J., "Biodegradable Polymers for Controlled Release of Drugs", Edited by M. Rosoff, Ch 2, pp. 53-95 **(1989)**
	233A	Riva, D. et al., "Oxybutynin Chloride in the Treatment of female Idiopathic ladder Instability, *Clin. Exp. Obst. Gyn*, **1984**, 37-42
	234	Coleman, M.M et al., "A Practical Guide to Polymer Miscibilit", *Polymers*, 31, 1187-1231 **(1990)**
	235	Drug Carrier Systems, by Roerdink et al., vol. 9, pp. 57-109 (1989)
	236	Leong, K.W. et al., "Polymeric Controlled Drug Delivery", *Advanced Drug Delivery Reviews.*, vol 1, 199-233 **(1987)**
	237	Handbook of Common Polymers, Compiled by Roff et al., **(1971)**, published by CRC Press, 72-81
	238	Wurster, D.E., "Air-Suspension Technique of Coating Drug Particles," *Journal of the American Pharmaceutcl Association*, 48, 451-454 **(Aug. 1959)**
	239	Wurster, D.E., "Preparation of Compressed Tablet Granulations by the Air-Suspension Technique II,", *Journal of the American Pharmaceutcl Association*, 49, 82-84 **(Feb.1960)**
	240	Pharmaceutical Sciences by Remington, 14th Ed., pp. 1626-1680 **(1970)**, published by Mack Publishing Co.
	241	Database WPI, Derwent Publication Ltd., London, GB, AN 94-031722, XP002096607
EXAMINER		DATE CONSIDERED

Form PTO-1449 Modified List of Patent and Publications Cited by Applicant (Use several sheets if necessary) U.S. Department of Commerce Patent and Trademark Office	Docket No. **ALZA-0143**	Application No. **10/645,715**
	Applicant **George V. Guittard, et al.**	
	Filing Date **August 20, 2003**	Group **1614**
	Confirmation No. **8447**	

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
	242	Database WPI, Derwent Publication Ltd., London, GB, AN 94-068306, XP002096606
	243	Gupta, S.K. et al., "Evidence for Site-Specific Presystemic Metabolism of Oxybutynin Following Oral Administration," *Clinical Pharmacology & Therapeutics*, 61, 2, **1997**, p. 227, XP002099744
	244	In the United States District Court for the Northern District of California, Alza Corporation, Plaintiff v. Impax Laboratories, Defendant, Case No. C-03-4032-VRW and C-03-4795, Decision Not to Dismiss California Declaratory Judgment Action, **No Date**
	245	IMPAX Notice of Paragraph IV Certification Letter regarding IMPAX Oxybutynin Chloride, 15 mg. Tablets w/Appendix, **July 25, 2003**
	246	IMPAX Notice of Paragraph IV Certification Letter regarding IMPAX Oxybutynin Chloride, 5 and 10 mg. Tablets w/Appendix, **August 19, 2003**
	247	In the United States District Court for the Northern District of California, Oakland Division, Case No. C-03-04032, Complaint for Patent Infringement w/Exhibit A, **September 4, 2003**
	248	In the United States District Court for the Northern District of California, Oakland Division, Case No. C-03-04032, Answer, Affirmative Defenses and Counterclaims of IMPAX Laboratories, Inc., **October 1, 2003**
	249	In the United States District Court for the Northern District of California, San Francisco Division, Case No. C-03-04032, Plaintiff ALZA Corporation's Reply to Defendant IMPAX Laboratories, Inc.'s Counterclaims, **November 13, 2003**
	250	In the United States District Court for the Northern District of California, San Francisco Division, Case No. C-03-04032, IMPAX'S Objections and Responses to Plaintiff's First Set of Interrogatories (Nos. 1-8), **May 20, 2004**
	251	In the United States District Court for the Northern District of California, Case No. C-03-4032 VRW, Order, **No Date**
	252	In the United States District Court, Northern District of California, San Francisco Division, Case No. C-03-04032, Plaintiff ALZA Corporation's Opening Memorandum of Law in Support of Claim Constructions, **December 15, 2004**
	EXAMINER	**DATE CONSIDERED**

Form PTO-1449 Modified List of Patent and Publications Cited by Applicant (Use several sheets if necessary) U.S. Department of Commerce Patent and Trademark Office	Docket No. **ALZA-0143**	Application No. **10/645,715**
	Applicant **George V. Guittard, et al.**	
	Filing Date **August 20, 2003**	Group **1614**
	Confirmation No. **8447**	

		OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)
	253	In the United States District Court for the Northern District of California, San Francisco Division, Case No. C-03-04032, IMPAX'S Objections and Responses to Plaintiff's First Set of Interrogatories (Nos. 1-8), **May 20, 2004**
	254	In the United States District Court for the Northern District of California, Case No. C-03-4032 VRW, Order, **No Date**
	255	In the United States District Court, Northern District of California, San Francisco Division, Case No. C-03-04032, Plaintiff ALZA Corporation's Opening Memorandum of Law in Support of Claim Constructions, **December 15, 2004**
	256	In the United States District Court, Northern District of California, San Francisco Division, Case No. C-03-04032, Declaration of Nicholas A. Peppas in Support of Plaintiff ALZA Corporation's Opening Memorandum of Law in Support of Claim Construction w/Exhibit A, **December 15, 2004**
	257	In the United States District Court, Northern District of California, San Francisco Division, Case No. C-03-04032, Declaration of David Eiseman in Support of Plaintiff ALZA Corporation's Opening Memorandum of Law in Support of Claim Construction w/Exhibits A-F, **December 15, 2004**
	258	In the United States District Court, Northern District of California, San Francisco Division, Case No. C-03-04032, Plaintiff ALZA Corporation's Objections and Responses to IMPAX Laboratories, Inc.'s First Set of Interrogatories, **January 10, 2005**
	259	In the United States District Court, Northern District of California, San Francisco Division, Case No. C-03-04032, Plaintiff ALZA Corporation's Supplemental Opening Memorandum of Law in Support of Claim Construction w/Exhibits A-J, **January 13, 2005**
	260	In the United States District Court, Northern District of California, San Francisco Division, Case No. C-03-04032, Defendant IMPAX Laboratories Inc.'s Responsive Claim Construction Brief, **March 10, 2005**
	261	In the United States District Court, Northern District of California, San Francisco Division, Case No. C-03-04032, Declaration of Mark I. Koffsky in Support of Defendant IMPAX Laboratories Inc.'s Responsive Claim Construction Brief, w/Exhibits A-B, **March 10, 2005**
	EXAMINER	**DATE CONSIDERED**

Form PTO-1449 Modified List of Patent and Publications Cited by Applicant (Use several sheets if necessary) U.S. Department of Commerce Patent and Trademark Office	Docket No. **ALZA-0143**	Application No. **10/645,715**
	Applicant **George V. Guittard, et al.**	
	Filing Date **August 20, 2003**	Group **1614**
	Confirmation No. **8447**	

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
	262	In the United States District Court, Northern District of California, San Francisco Division, Case No. C-03-04032, Declaration of Lewis J. Leeson in Support of Defendant IMPAX Laboratories Inc.'s Responsive Claim Construction Brief, w/Exhibit A, **March 10, 2005**
	263	IMPAX Notice of Paragraph IV Certification Letter regarding IMPAX Oxybutynin Chloride 5, 10 and 15mg. (and patent validity)Tablets w/Appendix, **July 19, 2005**
	264	In the United States District Court for the Northern District of West Virginia, ALZA Corporation, Plaintiff, v. Mylan Laboratories, Inc. and Mylan Pharmaceutical, Inc., C.A. # 1:03CV61(Judge Keeley), Post trial Memorandum Opinion and Order, **September 27, 2005,** 57 pages
	EXAMINER	**DATE CONSIDERED**

Form PTO-1449 Modified List of Patent and Publications Cited by Applicant (Use several sheets if necessary) U.S. Department of Commerce Patent and Trademark Office	Docket No. **ALZA-0143**	Application No. **10/645,715**
	Applicant **George V. Guittard, et al.**	
	Filing Date **August 20, 2003**	Group **1614**
	Confirmation No. **8447**	

U. S. PATENT DOCUMENTS

Examiner Initial		Document No.	Date	Name	Class	Subclass
	265	4,008,719	02/22/77	Theeuwes, et al.	128	260
	266	4,783,337	11/08/88	Wong, et al.	424	468
	267	5,135,757	08/04/92	Baichwal, et al.	434	465
	268	5,178,868	01/12/93	Malmqvist-Granlund, et al.	424	490
	269	5,407,686	04/18/95	Patel, et al.	424	468
	270	5,455,046	10/03/95	Baichwal	424	457
	271	5,532,278	07/02/96	Aberg, et al.	514	617
	272	6,124,355	09/26/00	Guittard, et al.	514	534

FOREIGN PATENT DOCUMENTS

Examiner Initial		Document No.	Date	Country	Translation YES	Translation NO
	273	AU 47732/90	07/12/90	Australia	X(Abstract)	
	274	WO 96/37202	11/28/96	PCT		

EXAMINER	**DATE CONSIDERED**

Form PTO-1449 Modified List of Patent and Publications Cited by Applicant (Use several sheets if necessary) U.S. Department of Commerce Patent and Trademark Office	Docket No. **ALZA-0143**	Application No. **10/645,715**
	Applicant **George V. Guittard, et al.**	
	Filing Date **August 20, 2003**	Group **1614**
	Confirmation No. **8447**	

U. S. PATENT DOCUMENTS

Examiner Initial		Document No.	Date	Name	Class	Subclass
	275	4,519,801	05/28/85	Edgren	604	892
	276	4,612,008	09/16/86	Wong, et al.	604	892
	277	4,994,276	02/19/91	Baichwal, et al.	424	440
	278	5,082,668	01/21/92	Wong, et al.	424	473
	279	5,128,143	07/07/92	Baichwal, et al.	424	464
	280	5,330,766	07/19/94	Morella, et al.	424	490
	281	5,399,359	03/21/95	Baichwal	424	464
	282	5,498,422	03/12/96	Nakamichi, et al.	424	451
	283	5,674,895	10/07/97	Guittard, et al.	514	534
	284	5,811,126	09/22/98	Krishnamurthy	424	498
	285	5,840,754	11/24/98	Guittard, et al.	514	534
	286	5,912,268	06/15/99	Guittard, et al.	514	534
	287	6,262,115 B1	07/17/01	Guittard, et al.	514	534

FOREIGN PATENT DOCUMENTS

Examiner Initial		Document No.	Date	Country	Translation YES	Translation NO
	288	WO 96/37202	11/28/96	PCT		

EXAMINER	**DATE CONSIDERED**

Form PTO-1449 Modified List of Patent and Publications Cited by Applicant (Use several sheets if necessary) U.S. Department of Commerce Patent and Trademark Office	Docket No. **ALZA-0143**	Application No. **10/645,715**
	Applicant **George V. Guittard, et al.**	
	Filing Date **August 20, 2003**	Group **1614**
	Confirmation No. **8447**	

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
	289	MYLAN Pharmaceuticals Inc. Notice of Paragraph IV Certification Letter regarding IMPAX Oxybutynin Chloride 10 mg. Tablets, **March 19, 2003**
	290	In the United States District Court for the Northern District of West Virginia Clarksburg Office, Civil Action No. 1-03CV61, Complaint for Patent Infringement (ALZA) W/Exhibit A, **May 2, 2003**
	291	MYLAN Pharmaceuticals Inc. Notice of Paragraph IV Certification Letter regarding IMPAX Oxybutynin Chloride 5 mg. Tablets, **May 21, 2003**
	292	In the United States District Court for the Northern District of West Virginia Clarksburg Office, Civil Action No. 1-03CV61, Answer, Defenses and Counterclaims of Defendant Mylan Laboratories Inc., **May 27, 2003**
	293	In the United States District Court for the Northern District of West Virginia Clarksburg Office, Civil Action No. 1-03CV61, Reply to MYLAN Pharmaceuticals Inc.'s Counterclaims Filed in Consolidated Action 1:03CV158, **July 30, 2003**
	294	In the United States District Court for the Northern District of West Virginia Clarksburg Office, Civil Action No. 1-03CV61, Mylan's Objections and Response to Plaintiff's First Set of Interrogatories, **September 18, 2003**
	295	In the United States District Court for the Northern District of West Virginia Clarksburg Office, Civ. Action No. 1-03CV61, ALZA's Response to Mylan's First Set of Interrogatories, **September 29, 2003**
	296	In the United States District Court for the Northern District of West Virginia Clarksburg Office, Civ. Action No. 1-03CV61, ALZA's Response to Mylan's Second Set of Interrogatories, **October 8, 2003**
	297	In the United States District Court for the Northern District of West Virginia Clarksburg Office, Civ. Action No. 1-03CV61, ALZA's Response to Mylan's Third Set of Interrogatories, **December 18, 2003**
	298	In the United States District Court for the Northern District of West Virginia Clarksburg Office, Civ. Action No. 1-03CV61, ALZA's Response to Mylan's Fourth Set of Interrogatories, **February 17, 2004**
EXAMINER		**DATE CONSIDERED**

Form PTO-1449 Modified List of Patent and Publications Cited by Applicant (Use several sheets if necessary) U.S. Department of Commerce Patent and Trademark Office	Docket No. **ALZA-0143**	Application No. **10/645,715**
	Applicant **George V. Guittard, et al.**	
	Filing Date **August 20, 2003**	Group **1614**
	Confirmation No. **8447**	

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
	299	In the United States District Court for the Northern District of West Virginia Clarksburg Office, Civil Action No. 1-03CV61, ALZA's Response to Mylan's Fifth Set of Interrogatories, **March 4, 2004**
	300	In the United States District Court for the Northern District of West Virginia Clarksburg Office, Civil Action No. 1-03CV61, ALZA's Supplemental Response to Mylan's Fifth Set of Interrogatories (Interrogatory No. 12), **March 19, 2004**
	301	In the United States District Court for the Northern District of West Virginia Clarksburg Office, Civil Action No. 1-03CV61, Mylan's Objections and Supplemental Responses to Plaintiff's first Set of Interrogatories, **March 21, 2004**
	302	In the United States District Court for the Northern District of West Virginia Clarksburg Office, Civil Action No. 1-03CV61, ALZA's Second Supplemental Response to Mylan's Fifth Set of Interrogatories (Interrogatory No. 8), **March 26, 2004**
	303	In the United States District Court for the Northern District of West Virginia Clarksburg Office, Civil Action No. 1-03CV61, ALZA's First Supplemental Response to Mylan's Third Set of Interrogatories (No. 6), **April 12, 2004**
	304	In the United States District Court for the Northern District of West Virginia Clarksburg Office, Civil Action No. 1-03CV61, Mylan's Pretrial Memorandum, **December 2, 2004**
	305	In the United States District Court for the Northern District of West Virginia Clarksburg Office, Civil Action No. 1-03CV61, Order Construing Claims and Denying Summary Judgment, **December 7, 2004**
	306	In the United States District Court for the Northern District of West Virginia Clarksburg Office, Civil Action No. 1-03CV61, Plaintiff (ALZA's) Pre-Trial Memorandum (w/Exhibits A-C),
	307	In the United States District Court for the Northern District of West Virginia Clarksburg Office, Civ. Action No. 1-03CV61, Markman Hearing Transcript, **December 29, 2004**
	308	In the United States District Court for the Northern District of West Virginia Clarksburg Office, Civil Action No. 1-03CV61, Mylan's Notice Pursuant to 35 U.S.C. § 282, **January 7, 2005**
EXAMINER		**DATE CONSIDERED**

Form PTO-1449 Modified List of Patent and Publications Cited by Applicant (Use several sheets if necessary) U.S. Department of Commerce Patent and Trademark Office	Docket No. **ALZA-0143**	Application No. **10/645,715**
	Applicant **George V. Guittard, et al.**	
	Filing Date **August 20, 2003**	Group **1614**
	Confirmation No. **8447**	

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
	309	United States District Court for the Northern District of West Virginia Clarksburg Office, Civil Action No. 1-03CV61, Trial Transcript, **April 18, 2005**
	310	In the United States District Court for the Northern District of West Virginia Clarksburg Office, Civil Action No. 1-03CV61, Mylan's Post-Trial Brief, with Exhibits A and B, **May 6, 2005**
	311	In the United States District Court for the Northern District of West Virginia Clarksburg Office, Civil Action No. 1-03CV61 , Plaintiff (ALZA) Post-Trial Reply Memorandum, **June 1, 2005**
	312	In the United States District Court for the Northern District of West Virginia Clarksburg Office, Civil Action No. 1-03CV61, Mylan's Post-Trial Reply Brief, **June 1, 2005**
	313	Mylan Letter to Judge Irene M. Keely regarding ALZA's arguments in its Post Trial Reply Brief, 1 page, **June 15, 2005**
	314	In the United States District Court for the Northern District of West Virginia Clarksburg Office, Civil Action No. 1-03CV61, Notice of Paragraph IV Certification US Patent 6,919,092 Oxybutynin Chloride Extended Release Tablets, 5 mg. and 10 mg. b, **July 22, 2005**
	315	In United States District Court for the Northern District of West Virginia Clarksburg Office, Civil Action No. 1-03CV61 , Plaintiff (ALZA) Post-Trial Reply Memorandum (Corrected), **No Date**

EXAMINER	**DATE CONSIDERED**

Form PTO-1449 Modified List of Patent and Publications Cited by Applicant (Use several sheets if necessary) U.S. Department of Commerce Patent and Trademark Office	Docket No. **ALZA-0143**	Application No. **10/645,715**
	Applicant **George V. Guittard, et al.**	
	Filing Date **August 20, 2003**	Group **1614**
	Confirmation No. **8447**	

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

	316	In the United States District Court for the Northern District of West Virginia, Alza Corporation, Plaintiff, V. Mylan Laboratories, Inc. Mylan Pharmaceuticals, Inc., Civil Action # 1:03CV61, Mylan's Supplemental Invalidity Contentions, Mylan's Supplemental Contentions Supporting the Invalidity of U.S. Patent No. 6,124,355, **January 29, 2003,** 26 pages
	317	In the United States District Court for the Northern District of West Virginia, at Clarksburg, Alza Corporation, Plaintiff, V. Mylan Laboratories, Inc. Mylan Pharmaceuticals, Inc., Civil Action # 1:03CV61, Mylan's Contentions Supporting the Invalidity of U.S. Patent No. 6,124,355, **December 29, 2003**
	318	In the United States District Court for the Northern District of West Virginia, Alza Corporation, Plaintiff, V. Mylan Laboratories, Inc. Mylan Pharmaceuticals, Inc., Civil Action # 1:03CV61, Mylan's Motion for Summary Judgment(#3) of Invalidity for Indefiniteness Under *Honeywell,* **July 14, 2004,** 12 pages
	319	In the United States District Court for the Northern District of West Virginia, Clarksburg Office, Alza Corporation, Plaintiff, V. Mylan Laboratories, Inc. Mylan Pharmaceuticals, Inc., Civil Action # 1:03CV61, Alza's Memorandum in Opposition to Defendant's Motion for Summary Judgment on Invalidity for Indefiniteness Under Honeywell (#3), **August 27, 2004,** 15 pages
	320	In the United States District Court for the Northern District of West Virginia, Clarksburg Office, Alza Corporation, Plaintiff, V. Mylan Laboratories, Inc. Mylan Pharmaceuticals, Inc., Civil Action # 1:03CV61, Mylan's Reply Memorandum in Support of its Motion for Summary Judgment (#3) of Invalidity for Indefiniteness Under *Honeywell,* **September 17, 2004,** 14 pages
	321	In the United States District Court for the Northern District of West Virginia, Clarksburg Office, Alza Corporation, Plaintiff, V. Mylan Laboratories, Inc. Mylan Pharmaceuticals, Inc., Civil Action # 1:03CV61, Mylan's Reply Memorandum in Support of its Motion for Partial Summary Judgment (#1) on the Threshold "Priority" Issue", With Attached Exhibit A, **July 14, 2004**

EXAMINER	**DATE CONSIDERED**

Form PTO-1449 Modified List of Patent and Publications Cited by Applicant (Use several sheets if necessary) U.S. Department of Commerce Patent and Trademark Office	Docket No. **ALZA-0143**	Application No. **10/645,715**
	Applicant **George V. Guittard, et al.**	
	Filing Date **August 20, 2003**	Group **1614**
	Confirmation No. **8447**	

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
	322	In the United States District Court for the Northern District of West Virginia, Clarksburg Office, Alza Corporation, Plaintiff, V. Mylan Laboratories, Inc. Mylan Pharmaceuticals, Inc., Civil Action # 1:03CV61, Mylan's Reply Memorandum in Support of Its Motion for Summary Judgment (#2) of Invalidity based on Inherent Anticipation, **July 14, 2004,** With attached Exhibits A & B
	323	In the United States District Court for the Northern District of West Virginia, Clarksburg Office, Alza Corporation, Plaintiff, V. Mylan Laboratories, Inc. Mylan Pharmaceuticals, Inc., Civil Action # 1:03CV61, Mylan's Motion for Summary Judgment (#5) of Invalidity Based Upon a Lack of Novelty over the Prior Art, Memorandum in Support of Mylan's Motion for Summary Judgment (#5) of Invalidity Based upon a Lack of Novelty over the Prior Art, **July 14, 2004**
	324	In the United States District Court for the Northern District of West Virginia, Clarksburg Office, Alza Corporation, Plaintiff, V. Mylan Laboratories, Inc. Mylan Pharmaceuticals, Inc., Civil Action # 1:03CV61, Alza's Memorandum in Opposition to Defendant's Motion for Summary Judgment (#5) of Invalidity based Upon a Supposed Lack of Novelty over the Prior Art, **August 27, 2004**
	325	In the United States District Court for the Northern District of West Virginia, Clarksburg Office, Alza Corporation, Plaintiff, V. Mylan Laboratories, Inc. Mylan Pharmaceuticals, Inc., Civil Action # 1:03CV61, Mylan's Reply Memorandum in Support of Its Motion for Summary Judgment (#5) of Invalidity Based Upon a Lack of Novelty over the Prior Art, **September 17, 2004,** with attached Exhibits A, B
	326	In the United States District Court for the Northern District of West Virginia, Clarksburg Office, Alza Corporation, Plaintiff, V. Mylan Laboratories, Inc. Mylan Pharmaceuticals, Inc., Civil Action # 1:03CV61, Plaintiff Alza Corporation's Opening Memorandum of Law in Support of Claim Construction, **July 14, 2004,** with attached Exhibits A thru I

EXAMINER	**DATE CONSIDERED**

Form PTO-1449 Modified List of Patent and Publications Cited by Applicant (Use several sheets if necessary) U.S. Department of Commerce Patent and Trademark Office	Docket No. **ALZA-0143**	Application No. **10/645,715**
	Applicant **George V. Guittard, et al.**	
	Filing Date **August 20, 2003**	Group **1614**
	Confirmation No. **8447**	

		OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)
	327	In the United States District Court for the Northern District of West Virginia, Clarksburg Office, Alza Corporation, Plaintiff, V. Mylan Laboratories, Inc. Mylan Pharmaceuticals, Inc., Civil Action # 1:03CV61, Plaintiff Alza Corporation's Memorandum in Reply to Defendants' Responsive Claim Construction Memorandum, **September 3, 2004,** with attached Exhibits N thru S
	328	In the United States District Court for the Northern District of West Virginia, Clarksburg Office, Alza Corporation, Plaintiff, V. Mylan Laboratories, Inc. Mylan Pharmaceuticals, Inc., Civil Action # 1:03CV61, Plaintiff Alza Corporation's Response to Defendants' "Markman" Claim Construction Memorandum, **August 20, 2004,** with attached Exhibits J thru M
	329	In the United States District Court for the Northern District of West Virginia, Clarksburg Office, Alza Corporation, Plaintiff, V. Mylan Laboratories, Inc. Mylan Pharmaceuticals, Inc., Civil Action # 1:03CV61, Mylan's "Markman" Reply Memorandum, **September 3, 2004**
	329 A	In the United States District Court for the Northern District of West Virginia, Clarksburg Office, Alza Corporation, Plaintiff, V. Mylan Laboratories, Inc. Mylan Pharmaceuticals, Inc., Civil Action # 1:03CV61, Mylan's Reply Memorandum in Support of its Motion for Partial Summary Judgment (#1) on the Threshold "Priority" Issue, **September 3, 2004**
	330	In the United States District Court for the Northern District of West Virginia, Clarksburg Office, Alza Corporation, Plaintiff, V. Mylan Laboratories, Inc. Mylan Pharmaceuticals, Inc., Civil Action # 1:03CV61, Mylan's "Markman" Claim Construction Memorandum, with attached Exhibits A thru C, **July 14, 2004**
	331	In the United States District Court for the Northern District of West Virginia, Clarksburg Office, Alza Corporation, Plaintiff, V. Mylan Laboratories, Inc. Mylan Pharmaceuticals, Inc., Civil Action # 1:03CV61, Mylan's Response to Alza's Claim Construction Memorandum, **August 20, 2004,** with attached Exhibits A, B.
	332	In the United States District Court for the Northern District of West Virginia, Clarksburg Office, Alza Corporation, Plaintiff, V. Mylan Laboratories, Inc. Mylan Pharmaceuticals, Inc., Civil Action # 1:03CV61, Mylan's Motion for Summary Judgment (#2) of Invalidity Based on Inherent Anticipation, **July 14, 2004**

EXAMINER	**DATE CONSIDERED**

Form PTO-1449 Modified List of Patent and Publications Cited by Applicant (Use several sheets if necessary) U.S. Department of Commerce Patent and Trademark Office	Docket No. **ALZA-0143**	Application No. **10/645,715**
	Applicant **George V. Guittard, et al.**	
	Filing Date **August 20, 2003**	Group **1614**
	Confirmation No. **8447**	

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
	333	In the United States District Court for the Northern District of West Virginia, Clarksburg Office, Alza Corporation, Plaintiff, V. Mylan Laboratories, Inc. Mylan Pharmaceuticals, Inc., Civil Action # 1:03CV61, Mylan's Motion for Partial Summary Judgment (#1) on the Threshold "Priority' Issue, **July 14, 2004,** w/attached Exhibit A
	334	In the United States District Court for the Northern District of West Virginia, Clarksburg Office, Alza Corporation, Plaintiff, V. Mylan Laboratories, Inc. Mylan Pharmaceuticals, Inc., Civil Action # 1:03CV61, Mylan's Motion for Summary Judgment (#5) of Invalidity based upon Lack of Novelty over the Prior Art, **July 14, 2004**
	335	In the United States District Court for the Northern District of West Virginia, Clarksburg Office, Alza Corporation, Plaintiff, V. Mylan Laboratories, Inc. Mylan Pharmaceuticals, Inc., Civil Action # 1:03CV61, Alza's Combined Memorandum in Opposition to Defendant's Motion for Summary Judgment on the Threshold Priority Issue (#1) and Invalidity based on Inherent Anticipation, **August 20, 2004,** with attached Exhibits A,B
	336	In the United States District Court for the Northern District of West Virginia, Clarksburg Office, Alza Corporation, Plaintiff, V. Mylan Laboratories, Inc. Mylan Pharmaceuticals, Inc., Civil Action # 1:03CV61, Mylan's Reply Memorandum in Support of Its Motion for Summary Judgment (#2) of Invalidity Based on Inherent Anticipation, **September 3, 2004**
	337	In the United States District Court for the Northern District of West Virginia, Clarksburg Office, Alza Corporation, Plaintiff, V. Mylan Laboratories, Inc. Mylan Pharmaceuticals, Inc., Civil Action # 1:03CV61, Plaintiff Alza Corporation's Memorandum in Reply to Defendant's Responsive Claim Construction Memorandum, **September 7, 2004**
	338	In the United States District Court for the Northern District of West Virginia, Alza Corporation, Plaintiff, V. Mylan Laboratories, Inc. Mylan Pharmaceuticals, Inc., Civil Action # 1:03CV61, Mylan's Supplemental Briefing on *Kennecott* and Alleged "Inherent Written Description", **November 2, 2004**
EXAMINER		**DATE CONSIDERED**

Form PTO-1449 Modified List of Patent and Publications Cited by Applicant (Use several sheets if necessary) U.S. Department of Commerce Patent and Trademark Office	Docket No. **ALZA-0143**	Application No. **10/645,715**
	Applicant **George V. Guittard, et al.**	
	Filing Date **August 20, 2003**	Group **1614**
	Confirmation No. **8447**	

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
	339	In the United States District Court for the Northern District of West Virginia, Alza Corporation, Plaintiff, V. Mylan Laboratories, Inc. Mylan Pharmaceuticals, Inc., Civil Action # 1:03CV61, Alza'a Memorandum in Response to Mylan's Supplemental Briefing on *Kennecott* and Alleged "Inherent Written Description", **November 13, 2004**
	340	In the United States District Court for the Northern District of West Virginia, Clarksburg Office, Alza Corporation, Plaintiff, V. Mylan Laboratories, Inc. Mylan Pharmaceuticals, Inc., Civil Action # 1:03CV61, Plaintiff's Pre-Trial Memorandum, **December 22, 2004**
	341	In the United States District Court for the Northern District of West Virginia, Clarksburg Office, Alza Corporation, Plaintiff, V. Mylan Laboratories, Inc. Mylan Pharmaceuticals, Inc., Civil Action # 1:03CV61, Mylan's Memorandum in Support of its Motion for Reconsideration, **December 23, 2004**
	342	In the United States District Court for the Northern District of West Virginia, Clarksburg Office, Alza Corporation, Plaintiff, V. Mylan Laboratories, Inc. Mylan Pharmaceuticals, Inc., Civil Action # 1:03CV61, Mylan's Motion for Reconsideration of the Court's Ruling on Summary Judgments # 1 and #2, **December 24, 2004**
	343	In the United States District Court for the Northern District of West Virginia, Clarksburg Office, Alza Corporation, Plaintiff, V. Mylan Laboratories, Inc. Mylan Pharmaceuticals, Inc., Civil Action # 1:03CV61, Mylan's Motion for Reconsideration of the Court's Ruling on Summary Judgments #1 and #2, Mylan's Memorandum in Support of its Motion for Reconsideration, **January 24, 2005**
	344	In the United States District Court for the Northern District of West Virginia, Clarksburg Office, Alza Corporation, Plaintiff, V. Mylan Laboratories, Inc. Mylan Pharmaceuticals, Inc., Civil Action # 1:03CV61, Mylan's Reply Memorandum in Support of its Motion for Reconsideration, **January 31, 2005**
EXAMINER		**DATE CONSIDERED**

Form PTO-1449 Modified List of Patent and Publications Cited by Applicant (Use several sheets if necessary) U.S. Department of Commerce Patent and Trademark Office	Docket No. **ALZA-0143**	Application No. **10/645,715**
	Applicant **George V. Guittard, et al.**	
	Filing Date **August 20, 2003**	Group **1614**
	Confirmation No. **8447**	

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
	346	In the United States District Court for the Northern District of West Virginia, Clarksburg Office, Alza Corporation, Plaintiff, V. Mylan Laboratories, Inc. Mylan Pharmaceuticals, Inc., Civil Action # 1:03CV61, Plaintiff's Post Trial Memorandum(Corrected) **June 1, 2005**
	347	Ditropan XL NTS: Projections and Annuals, **Defendant's Exhibit DX 2012**
	348	Letter from Michael B. Chancellor, M.D. to Richard McCormick-Re: ALZA v. Mylan [Ditropan XL], **Defendant's Exhibit DX 2016**
	349	Quarterly TX Market Share (Updated) , **Defendant's Exhibit DX 2017**
	350	Market Share Trends, **Defendant's Exhibit DX 2018**
	351	J & J Worldwide Advertising Group media Budget Control Record(MBCR), Ditropan, **Defendant's Exhibit DX 2019**
	352	DX 2020-Articles teaching that a Lower Dose of Oxybutynin is Effective and has Fewer Side Effects, **Defendant's Exhibit DX 2020**
	353	Ditropan XL: BMEs as a Percent of Net Trade Sales, **Defendant's Exhibit DX 2024**
	354	Alza Corporation Physician Advisory Board Meeting, Phoenix, AZ, **1998, Defendants Exhibit DX 2029**
	355	Ditropan-Xl TRX Market Share Compared to Rebates (%NTS), **Defendants Exhibit DX 2025**
	356	Chancellor, M.B. MD., "What is Really New in Overactive Bladder?, **February 25, 2004, Defendant's Exhibit DX 2038**
EXAMINER		**DATE CONSIDERED**

Form PTO-1449 Modified List of Patent and Publications Cited by Applicant (Use several sheets if necessary) U.S. Department of Commerce Patent and Trademark Office	Docket No. **ALZA-0143**	Application No. **10/645,715**
	Applicant **George V. Guittard, et al.**	
	Filing Date **August 20, 2003**	Group **1614**
	Confirmation No. **8447**	

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
	357	AWP Price Per Day: TID Oxy Products, **Defendant's Exhibit's DX 2039**
	358	Ditropan ® Xl, Recommendation for Additional Clinical Study, **Defendant's Exhibit 2056,**
	359	Ditropan XL: NTS Compared to Profits, **Defendant's Exhibit DX 2061**
	360	Ditropan XL Profits Compared to J & J Investment, **Defendant's Exhibit DX 2062**
	361	Ditropan XL Financial Data, **Defendant's Exhibits DX 2063**
	362	Ditropan-XL TRX Market Share Compared to BME/Selling (%NTS), **Defendant's Exhibits DX 2065**
	363	Ditropan Xl ® vs Detrol ® Spit Study, Post-Launch (Stage 5), **Defendant's Exhibit DX 2067**
	364	Physicians' Desk Reference, PDR®, 42 Edition, **1988,** Ditropan Tablets and Syrup

EXAMINER	**DATE CONSIDERED**